

### **REMARKS/ARGUMENTS**

Claim 1 has been amended as set forth in the above "Listing of the Claims." As amended, the claims are supported by the specification and the original claims. In particular, the amendments to claim 1 are supported, for example, at page 7, lines 12-23 and page 14, lines 11-12. Thus, upon entry of the amendments, claims 1-13, 15 and 16 will be pending.

#### **Rejection Under 35 U.S.C. § 112, First Paragraph**

Applicant respectfully traverses the rejection of claim 16 under 35 U.S.C. § 112, first paragraph, for containing subject matter allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time of filing of the Application. In particular, it is alleged in the Office Action at page 6 that claim 16 is new matter and thus fails to comply with the written description requirement. Applicant respectfully traverses.

It is noted that on Page 4 of the response submitted on September 8, 2003, Applicant provided support for the addition of Claim 16. Specifically, support may be found in Example 1 and Figure 1 of the application as filed. M.P.E.P. § 2163.06 states that:

***"If an applicant amends or attempts to amend the abstract, specification or drawings of an application, an issue of new matter will arise if the content of the amendment is not described in the application as filed. Stated another way, information contained in any one of the specification, claims or drawings of the application as filed *may be added to any other part of the application without introducing new matter.*" (Emphasis added.)***

The alleged basis of the present rejection is that the parent application (US Serial No. 08/742,943) does not contain SEQ ID NO: 3. However, SEQ ID NO: 3 of the instant application, as provided in the Sequence Listing filed on May 3, 2001, contains the sequence of the nucleic acid construct depicted in FIG. 1, which is identical to FIG. 1 of US Serial No. 08/742,943, as filed. Similarly, and with reference to the Examiner's allegation under 35 U.S.C. § 132 that the

amended sequence listings filed on January 30, 2001 and May 8, 2001 introduce new matter (Office Action, page 6), SEQ ID NO: 4 contains the sequence listing of the target sequence depicted in FIG. 1, and SEQ ID NO: 5 contains the sequence listing of the Sm protein binding sequence depicted in FIG. 1. Consequently, all of the information provided in the amended sequence listings are contained in FIG. 1 of US Serial No. 08/742,943 as filed and do not constitute new matter. Thus, Applicant respectfully submits that claim 16 meets the written description requirement of 35 U.S.C. §112, first paragraph. Accordingly, withdrawal of the rejection is respectfully requested.

### **Rejection Under 35 U.S.C. § 102**

Applicant respectfully traverses the rejection of claims 1-13 under 35 U.S.C. 102(a) as allegedly being anticipated by Michienzi et al. (hereinafter "Michienzi"). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration (In re Spada, 15 USPQ 2d 1655 (Fed. Cir. 1990), In re Bond, 15 USPQ 2d 1566 (Fed. Cir., 1990)). Applicant respectfully submits that Michienzi does not teach all elements of claims 1-13.

Applicant's invention as claimed in amended claim 1 distinguishes from the teachings of Michienzi by requiring an antisense nucleic acid that suppresses gene expression and is flanked by the stem loop structures, with the proviso that the antisense nucleic acid *is not within a stem loop structure*. Applicant defines stem loop structures at page 7, lines 12-23 of the instant application as follows:

The "stem loop" structures refer to nucleic acid structures that have folding patterns which form hairpins *and flank* the antisense targeting sequence. (Emphasis added)

Use of the term "and" indicates that a stem loop structure as defined by the specification necessarily includes both folding patterns which form hairpins and that they flank the antisense

targeting sequence. Thus, an antisense targeting sequence cannot fall within a stem loop, if by definition, the stem loop flanks it. Furthermore, Applicant describes Figure 1 at page 14, lines 11-12 of the Specification as “an antisense targeting core [being] substituted for the Sm protein binding site *between* the two naturally occurring U1 snRNA hairpins.” (Emphasis added)

Conversely, Michienzi teaches nucleic acid constructs in which a hammerhead ribozyme sequence substitutes part of the stem loop III of U1 snRNA. As acknowledged by the Examiner on page 3 of the Office Action, “...the ribozyme/antisense construct of Michienzi, depicted in bold within the U1-Rz RNA construct, is a part of stem-loop structure III...” Even where Michienzi used antisense to control for the antisense effect, it was done by substitution of part of a stem loop. Accordingly, all constructs taught by Michienzi contain stem loops into which a ribozyme/antisense has been substituted. Accordingly, Michienzi cannot anticipate Applicant's invention.

Finally, the Examiner's attention is drawn to three specific requirements in the language of claim 1. First, it is required that the antisense nucleic acid be *flanked* by the stem loop structures. Second, it is required that the antisense nucleic acid suppress gene expression. Third, it is required that the antisense nucleic acid *not* be within a stem loop structure. Michienzi does not describe administration of a ribozyme utilizing a construct with these characteristics.

As Michienzi does not teach all of the elements of the claimed invention, it is respectfully submitted that Michienzi cannot anticipate the claimed invention under 35 U.S.C § 102(a) and withdrawal of the rejection is therefore respectfully requested.

In re Application of:  
Harry C. Dietz  
Application No.: 09/163,289  
Filed: September 29, 1998  
Page 7

PATENT  
Attorney Docket No.: JHU1400-1

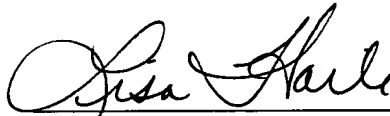
**CONCLUSION**

In summary, for the reasons set forth herein, Applicant maintains that claims 1-13, 15 and 16 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

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